

REMARKS

The Examiner has noted that a certified copy of Swedish Patent Application No. 0100938-0 has not been submitted. The Applicant is in the process of obtaining a certified copy of the priority document. Once the certified copy is received, it will be filed with the United States Patent and Trademark Office.

The Examiner has stated that Information Disclosure Statement filed on September 12, 2003 fails to comply with the provisions of 37 CFR §1.97, 1.98 and MPEP §609 because it does not include a concise explanation of the relevance of the information of each patent, publication, or other information listed that is not in the English language.

Attached hereto is a new Information Disclosure Statement. Also enclosed is a copy of the PCT International Search Report, a copy of which was previously submitted on September 12, 2003, where German Patent No. DE19742725 (ABTS, HARRY FRANK, DR.) was first cited.

The drawings have been objected to because the label for the X-axis in Figure 8 is not in English. The drawings have been amended to overcome the Examiner's objection.

The specification has been objected to due to a number of informalities. The specification has been amended to overcome the Examiner's rejections.

Claims 31, 37, 39, 41 and 45-50 have been objected to due to informalities. Claims 39 has been amended to overcome the Examiner's objection and claims 31, 37, 41 and 45-50 have been canceled.

Claims 31, 37, 47-50 have been rejected under 35 U.S.C. §112, second paragraph as being indefinite. Claims 31, 37, 47-50 have been canceled. Thus, the Applicants request that the Examiner withdrawn the §112, second paragraph rejection.

Claims 31, 37 and 47-50 have been rejected under 35 U.S.C. §101 because the claimed recitation of use, without setting forth any steps involved in the process, results in an improper definition of process. Claims 31, 37, 47-50 have been canceled. Thus, the Applicants request that the Examiner withdrawn the §101 rejection.

Claims 39, 41, 45 and have been are rejected under 35 U.S.C. §112, first paragraph, enabling requirement.

A Western blot experiment showing that one of the monoclonal antibodies (S106) disclosed in the specification on p. 9, l. 31 and in Example 5, actually binds to fusion proteins present in human cancer cells has been conducted. As disclosed in the specification this antibody was actually produced using the SCCA1/A2 fusion protein described in the application. If the Examiner requests the data can be entered in the form of an affidavit by the Inventor.

Claims 31, 37, 39 and 45-51 have been rejected under 35 U.S.C. §102(b) as being anticipated by Nawata et al. (Electrophoresis, 1999, 20:614-617). Claims 37, 39, 41 and 45-48 have been rejected under 35 U.S.C. §102(b) as being anticipated by Matsuda et al. (Cancer, 1990, 65: 2261-2265). Claims 37, 39 and 45-48 have been rejected under 35 U.S.C. §102(b) as being anticipated by Cataltepe et al. (Clin. Chim. Acta, 2000, 295:107-127).

The Examiner's rejection is respectfully traversed.

Claims 39 has been amended to overcome the Examiner's rejection and claims 37 and 45-50 have been canceled.

The claim as now amended is directed to a method for diagnosing the presence or absence of a squamous cell carcinoma by detecting the presence and concentration of the SCCA1/SCCA2 fusion protein in a human sample using a monoclonal antibody specific for the

SCCA1/SCCA2 fusion protein only. The monoclonal antibody has no affinity for SCCA1 or SCCA2, and wherein the SCCA1/SCCA2 fusion protein is coded by the exons 2-7 of the SCCA1 gene fused to exon 8 of the SCCA2 gene. The amino acid sequence of the SCCA1/SCCA2 fusion protein being (SEQ ID NO: 1).

Nawata et al. (Electrophoresis, 1999, 20:614-617), Matsuda et al. (Cancer, 1990, 65: 2261-2265), and Cataltepe et al. (Clin. Chim. Acta, 2000, 295:107-127) do not disclose using a monoclonal antibody specific for the SCCA1/SCCA2 fusion protein only, wherein the monoclonal antibody has no affinity for SCCA1 or SCCA2, and wherein the SCCA1/SCCA2 fusion protein is coded by the exons 2-7 of the SCCA1 gene fused to exon 8 of the SCCA2 gene, the amino acid sequence of the SCCA1/SCCA2 fusion protein being (SEQ ID NO: 1).


The Examiner states that the cited references would have....(shown the Applicants' invention), but there is no specific teachings of the Applicants' invention that the Examiner cites. The Examiner simply makes a statement that the references would work if they did something else and thus, the Applicants' invention is not anticipated by the cited references.

In view of the foregoing, the Applicants respectfully contend that the present invention is not anticipated by Nawata et al. (Electrophoresis, 1999, 20:614-617), Matsuda et al. (Cancer, 1990, 65: 2261-2265), and Cataltepe et al. (Clin. Chim. Acta, 2000, 295:107-127). Accordingly, Applicants believe that pending claim 39 is now deemed to be patentable over the prior art of record and should be allowed.

The application is now considered to be in condition for allowance, and an early indication of same is earnestly solicited.

The Commissioner is authorized to charge any further extension and/or fee that is required to Deposit Order Account 19-0079.

Respectfully submitted,


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